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10/677,956	10/01/2003	Suzanne Zebedee	323-100US D	9260

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EXAMINER	
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ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/677,956	ZEBEDEE ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *124-136 and 140-147* is/are pending in the application.

4a) Of the above claim(s) *127,128,132-136 and 145* is/are withdrawn from consideration.

5)☒ Claim(s) *142* is/are allowed.

6)☒ Claim(s) *124-126,129-131,140,141,143,144,146 and 147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 124-136, 140-147 are pending in the application.

2. Claims 124-126, 129-131, 140-144, 146, and 147 are under consideration.

3. This action is Supplemental to the action of August 10, 2007. In that action, claim 42 was indicated to be objected to, but no objection was made to the claim. This action is made to clarify the status of that claim.

Specification

4. **(Prior Objection- Withdrawn)** The disclosure was objected to because of the following informalities: the Title is Missing from the first page of the specification. In view of the submission of 9/7/06, the objection is withdrawn.

5. **(Prior Objection- Withdrawn)** The amendments filed April 3 and May 5, 2006 were objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. Applicant's arguments in traversal are found persuasive. The objection is withdrawn.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **(Prior Rejection- Withdrawn)** Claims 124-126 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicant's arguments that those in the art would have

understood what was meant by the phrase "at early times after infection" are found persuasive. In view of the arguments in traversal, the rejection is withdrawn.

8. **(Prior Rejection- Withdrawn)** Claims 124-126, 129-131, 137-144, 146, and 147 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 124 and 129 are representative. In view of the amendments to the claims, the rejection is withdrawn.

9. **(Prior Rejection- Maintained in part)** Claim 131 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant asserts that the clear because CAP-B is one of several subsections of SEQ ID NO: 73. This argument is not found persuasive. On page 27 of the substitute specification, the CAP-B protein is identified not as any protein comprising residues 21-40 of SEQ ID NO: 73, but to a fusion protein comprising both the indicated section of SEQ ID NO: 73, and GST. It is not clear from claim 131 if the claim is intended to read on any polypeptide comprising the indicated residues of SEQ ID NO: 73, or on a polypeptide comprising both the GST protein and residues 21-40 of SEQ ID NO: 73. Because it is not clear from the claims if the reference to "CAP-B" is intended to require the presence of GST, the rejection is maintained.

It is suggested that reference to "CAP-B" be deleted.

The claim was also rejected because it is both unclear what effect the inclusion of the reference to CAP-N has on the antigen of subpart d of the claim. Moreover, it was also indicated that there does not appear to be a definition as to what a CAP-N antigen comprises in the application. Applicant's arguments in traversal in combination with the teachings in the application are found persuasive. This portion of the rejection is therefore withdrawn.

10. **(New Rejection –Necessitated by Amendment)** Claims 124-126, 129-131, 141, 143, 144, 146, and 147 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims have been amended to read on methods comprising a step of "detecting the presence of any of said immunoreaction product formed and early seroconversion." It is not clear from this amendment if the Applicant is intending the method comprise two separate detection steps, or if the Applicant intends that the early seroconversion is detected by way of the detection of the immunoreaction product if any. It is suggested that the claims be amended to indicate "whereby detection of immunoreaction product indicates the presence of the NANBV associated seroconversion."

11. **(New Rejection –Necessitated by Amendment)** Claim 140 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim includes a step of "initiating an immunoreaction admixture." It is unclear how an admixture can be

initiated. It appears that the Applicant intended to amend the claim to read "initiating an immunoreaction" as was done in other pending claims.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. **(Prior Rejection- Maintained)** Claims 124-126, and 129-131 were rejected under 35 U.S.C. 102(e) as being anticipated by Houghton et al., (U.S. 5,350,671). It is noted that the claims have been amended to require that the method be performed on a number of different samples from different donors. This amendment is not deemed to avoid the rejection as the reference teaches the use of the described method for the detection of anti-HCV antibodies as a diagnostic for the presence of viral infection (see e.g., column 1, lines 34-40), which would have been understood by those in the art to indicate that the method was to be practiced repeatedly on different samples from different donors. The amendment therefore fails to overcome the rejection.

The Applicant traverses the rejection on the basis that the reference does not teach the detection of seroconversion at early times after infection, and that the teachings of the reference fail to suggest that the use of the capsid antigens would result in detection of seroconversion at

such early times. These arguments are not found persuasive. The reference teaches a method comprising the steps and components required by the present claims. The differences between the method described in the reference, particularly in the claims of the reference previously identified, and the claimed method is that the reference does not appear to recognize certain benefits that flow from the performance of the method disclosed therein. However, because performance of the method would inherently achieve the results required by the present claims, the Applicant's arguments that the reference does not recognize the benefits fails to overcome the rejection. See e.g., MPEP § 2112 II (indicating that an inherent feature of the prior art need not be recognized at the time of invention in order for the reference to anticipate a claimed invention). Because the reference teaches a method for the detection of anti-HCV antibodies through the use of capsid antigens as required by the present claims, and as such a method would inherently achieve the benefits of using this antigen as a target antigen in a seroconversion assay, the argument is not found persuasive and the rejection is maintained.

14. **(Prior Rejection- Maintained)** Claims 124-126, 129, and 131 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang (U.S. 5,436,126). No arguments have been presented specifically with respect to this rejection. Applicant's arguments with respect to the Houghton reference as described above have been considered, but have not been found persuasive for the same reasons as indicated above. The rejection is therefore maintained. The Declaration by Helting is noted. However, a declaration showing prior conception is not found persuasive where the reference is claiming the invention of the rejected claims. See e.g., MPEP 715.05. The rejection is therefore maintained.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. **(Prior Rejection- Maintained)** Claims 124-126, 129-131, 138, 141, 143, 144, 146, and 147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton as applied to claims 124, 125, 126, 129, and 131 above. The Applicant traverses the rejection on the basis that Houghton does not specifically teach that the capsid protein was uniquely effective for the detection of early seroconversion, and appears to be asserting unexpected results in the combination of the C-100-3 and the capsid antigen in the two antigens were capable of detecting different stages of infection. These arguments have been considered but are not found persuasive.

As was previously indicated, the reference teaches the use of both the C-100-3 antigen and the core antigen for the detection of anti-HCV antibodies. It would therefore have been obvious to those of ordinary skill in the art to combine these antigens, useful for the same purpose, in a combined method for the detection of HCV antibodies in a sample.

Further teachings in the art indicate that the C-100-3 assay was used in the art for the diagnosis of HCV infection, and that it was known in the art that the use of C-100-3 antigen alone did not detect all cases of HCV infection. See e.g., the Helting declaration, page 4, and Weiner et al., Lancet 335: 1-3 (of record in the March 2006 IDS, and cited in the Helting Declaration- indicating that the C-100-3 immunoassay was effective for HCV diagnosis, but that

detection based only on detection of C-100-3 antibodies did not catch every case of infection). Moreover, the teachings of Houghton demonstrate that it was known in the art to combine assays for multiple HCV antigens, and demonstrate four antigens that were also useful for detection of HCV infection. See e.g., the claims previously described (teaching the capsid antigen), and columns 133-136 (teaching 5-1-1, C-100-3, and C33c antigens). Because it was known in the art to combine assays for the detection of a plurality of antigens, and as the art provides motivation for the detection of antibodies against HCV antigens other then the C-100-3 antigen, those in the art would have had adequate motivation to combine immunoassays for the detection of both the capsid and the C-100-3 antigen as a means to increase the overall efficacy for the diagnosis of HCV infection.

That the core antigen happened to detect antibodies at an earlier time than the C-100-3 antigen would have been an additional benefit to those in the art following the suggestions in the art. See e.g., MPEP 2145 II. The teachings of Houghton teach the use of the capsid antigen. At the time that the current application was filed, the C-100-3 antigen was the antigen used in the art. See e.g., Wiener, supra. Thus, those in the art would have been motivated to combine these antigens in the effort to improve the diagnostic test already used in the art, and thus any additional resulting benefit would have been an additional advantage of the combination suggested by the teachings in the art.

For the reasons above, and the reasons of record, the rejection is maintained.

17. **(Prior Rejection- Maintained)** Claims 124-126, 129-131, 138, 141, 143, 144, 146, and 147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang as applied to claims

124-126, 129, and 131 above, further in view of Houghton et al., (U.S. 5,350,671). The claims have been described above. Applicant traverses this rejection on the basis that the reference is not prior art over the present claims, and that the reference does not teach the use of C-100-3 with the capsid antigen.

With respect to the assertions regarding the use of Wang as prior art, it was noted that Wang does teach the detection of HCV antibodies using a capsid antigen as a diagnostic for HCV infection. Such would inherently include the screening of multiple samples from multiple donors as those in the art would have performed such a diagnostic method throughout the patient population potentially infected with the virus. Moreover, the simple performance of the method on such would also inherently result in the detection of HCV seroconversion at earlier times relative to the infection than would use of the C-100-3 antigen alone. Thus, because the reference claims the invention (the use of the capsid antigen for detection of HCV antibodies) to which the declaration is directed, the declaration is not found persuasive.

With respect to the combination of the capsid and C-100-3 antigens, the combination would have been obvious over the teachings in the references cited for the reasons indicated previously. The Applicant's additional arguments are not found persuasive for the reasons described with respect to the Houghton reference above.

The rejection is therefore maintained for the reasons above and the reasons of record.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

19. In the prior action, Applicant was advised that should claim 140 and 142 be found allowable, claim 137 and 139 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. It is noted that claims 137 and 139 are no longer pending in the application.

Conclusion

20. Claim 142 appears allowable over the prior art.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas/
Patent Examiner, AU 1648